

REMARKS

Currently Claims 1-16, 18-28, 55 and 57-59 are pending and stand rejected under the Office Action mailed July 3, 2008. Claims 4-5, 9, 18, 20, 22, 24-25 and 27 are withdrawn as being directed to a non-elected species, but depend from a generic claim. Applicants note that Claim 24 is not addressed in the Outstanding Office Action, but given that the subject matter of Claim 24 is not encompassed by the previously elected species, Applicants assume Claims 24 is withdrawn as well. In view of the above amendment and the following remarks, reconsideration is respectfully requested.

Rejection under 35 USC § 103

Claims 1, 6 and 8 were previously rejected under 35 USC § 103 based on a combination of US 5,523,316 to Gan et al. ("Gan") with Arshinoff (1996) ("Arshinoff") and the Revision of Pharmacology (2002) ("ROP"). Based on the prior response, this rejection was withdrawn, but a new rejection under 35 USC § 103 based on Gan, Corbett et al. (British Journal of Ophthalmology, 1994), US Patent 4,474,811 to Masuda and ROP has been presented.

Applicants respectfully submit that the hypothetical combination of the cited references falls short of the present invention. The primary reference, Gan, discloses intraocular irrigation solutions including one or more drugs for controlling intraocular pressure in a BSS Plus® carrier solution. The drugs for controlling intraocular pressure include beta-blockers, alpha adrenergic agonists, muscarinic agonists, carbonic anhydrase inhibitors, angiostatic steroids and prostaglandins. As noted in prior responses, Gan does not teach *combining* IOP reducing agent(s) with another agent that is an anti-inflammatory, analgesic or mydriatic agent, as claimed. Gan is directed to irrigation solutions for controlling intraocular pressure, and not to the use of solutions of *multiple* agents selected to control multiple physiologic functions

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associated with ophthalmologic surgery. Can also does not disclose continuous irrigation (Claim 1), concentrations of agents of no more than 100,000 nanomolar (Claim 28), or teach that *mydriatic agents and anti-inflammatory agents should be combined* in the solution (Claim 57).

Because of the above shortcomings, the Office Action relies on Corbett for disclosing that cataract surgery is performed more easily if mydriasis can be maintained during the procedure, and Masuda for teaching that anti-inflammatories may be used intraoperatively to reduce inflammation. However, Masuda is clearly directed to a topical “ophthalmic solution” rather than an intraocular irrigation solution, as evidenced by the teaching that preservatives may be used (Column 6, lines 1-8), which are necessary for multi-use ophthalmic drops but typically strictly avoided for intraocular administration due to toxicity concerns. Finally, ROP is relied upon because of disclosing that NSAIDs can be used to inhibit miosis during cataract surgery, but this is disclosed only in the context of “topical” application of the NSAIDs. (ROP at 29).

Applicants initially note that the rejection is based on drawing together all of the differing aspects of the presently claimed invention from a large number of references. A patent claiming several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the art. *KSR Int’l v. Teleflex, Inc.*, 127 S. Ct. 1727, 82 USPQ2d 1385 (2007). The only road map for combining these references, which address very different aspects of ophthalmology, in this fashion is Applicants’ own disclosure. This would involve the impermissible use of hindsight. *Ex Parte Crawford et al*, Appeal 20062429, Decided May 30, 2007. Applicants’ respectfully submit that no *prima facie* case of obviousness has been set forth for at least this reason.

Further, the intracameral chamber of the eye contains delicate structures; surgeons make changes in the methods of treatment employed during intraocular surgery only with caution. Applicants previously presented two references that Applicants submit teach away from the

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present invention. While the Office Action did not find these references sufficient as teaching away from the invention (with which conclusion Applicants disagree), these references, at a minimum, clearly show that different medications cannot be routinely combined by those of skill in the art, as proposed in the Office Action, with a predictability of success. As acknowledged in the Office Action, Hirowatari teaches that repeated instillation of mydriatic and anti-inflammatory solutions may damage the corneal epithelium. Flach reports on a number of instances of corneal complications, including corneal melting, from topical NSAID treatment. These references exemplify that those of skill in the art would not conclude that combining the various solutions cited in the Office Action would have yielded predictable results, again illustrating that the invention is not a mere obvious combination of prior art. *KSR Int'l.*

For all of the forgoing reasons, applicants submit that no *prima facie* case of obviousness has been established, and the rejection should be withdrawn.

With respect to Claims 57 (and 58-59 dependent there from) in particular, which require the combination of a mydriatic agent with an anti-inflammatory agent, Applicants note that the Office Action relies on Masuda and ROP for the inclusion of an anti-inflammatory agent in an intraocular irrigation solution together with a mydriatic agent. Masuda and ROP each disclose topically delivered NSAIDs, as addressed above, rather than intraocular irrigants. Applicants submit that the rejection of these claims is further deficient in this regard as well.

Nonstatutory Obviousness-Type Double Patenting Rejection

Claims 1 and 28 were rejected for nonstatutory obviousness-type double patenting based on various claims of US Patents 6,261,279, 6,413,961 and 6,420,432, all in view of Gan, Corbett, Masuda and ROP. Each of these noted US Patents was issued to inventors Demopoulos et al. and assigned to the assignee of the current application. The Demopoulos patents each claim perioperative methods for inhibiting pain and/or inflammation during surgical procedures, or

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solutions for inhibiting pain and/or inflammation, using one or a plurality of anti-inflammatory/anti-pain agents. The particular agents claimed vary for each of these patents. However, in all cases the agents claimed are anti-inflammatory and/or anti-pain agents. In no cases do the noted Demopulos patents claim the use of mydriatic agents or agents for reducing IOP, at least one of which mydriatic agents and IOP reducing agents is required in each of independent Claims 1 and 28.


Further, the methods of the presently pending claims would not be obvious over the claims of the Demopulos patents, which are directed solely to pain and inflammation and not to reducing IOP and/or promoting mydriasis as required by Claims 1 and 28. Consideration of Gan, Corbett, Masuda and ROP do not change this outcome, because of the shortcomings of the cited references described above. Accordingly, it is respectfully submitted that present Claims 1 and 28 are not obvious over the claims of the commonly owned cited patents, alone or in view of the Gan, Corbett, Masuda and ROP references.

Closure

In view of the above amendment and remarks addressing the new rejection, Applicants respectfully request reconsideration and allowance of all pending claims, inclusive of Claims 1-16, 18-28, 55 and 57-59. Should the Examiner have any questions or wish to discuss any matter, he is invited to telephone the undersigned attorney.

Respectfully Submitted,

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